K013817
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SOL WEISS, M.D., INC.
7012 RESEDA BOULEVARD, SUITE A
RESEDA, CALIFORNIA 91335
TELEPHONE (818)346-1515
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510(k) Summary

Intended use:

- The intended use is interconnection of devices for transmission of light
- The intended use is to illuminate area of view

Physical / Technical Comparison:

- Have the same intended use of transmitting light
- Manufactured through injection molding
- Made with same materials
- Maintain same rigidity of part
- Both have clear plastic for viewing
- Both have windows that allow heat to escape.

Differences:

- Rests in the lateral wall protector to keep viewing clear
- Rests in the lateral wall protector affording less chance of interfering with view of the vagina during procedures
- Does not alter the utilization,safety or efficacy of the Nu-Spec D while affording light for visualization
- Glo-Spec portable connector has no body or membrane contact. Kleenspec connector as part of the handle has contact with the body surface.
- Glo-Spec portable connector will allow for other different light sources to be used (i.e. penlights, etc.) Welch Allyn's Kleenspec only permits their transformer and equipment as a light source.
- Glo-Spec portable connector place is above and out of area where bleeding may contaminate this device

Performance Summary:

- Constructurally equivalent to the Welch Allyn's Kleenspec, and other predicate devices which have already been subjected to millions of applications

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The Glo-Spec complies with all acceptance criteria listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2001

Sol Weiss, M.D.
Sol Weiss, M.D., Inc.
7012 Reseda Boulevard, Suite A
RESEDA CA 91335

Re: K013817
Trade/Device Name: Glo-Spec™
Connector, Vaginal Speculum
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstretric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: 85 HIB
Dated: November 12, 2001
Received: November 16, 2001

Dear Dr. Weisse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013817

Device Name: Glo-Spec; alternative name is Glo-Speck

Indications for use:

The intended use is the interconnection of devices
for transmission of light.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON
ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lieberman

(Division Sign-Off)
Division of [redacted]
and Radiological Devices
510(k) Number K013817

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)